K091599

JUL 20 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The Assigned 510(k) Number is: Pending

1. Submitter Information

- **Manufacturer Name:**
  Beijing Choice Electronic Technology Co., Ltd.
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  Fuxing Road , No. A36
  Beijing, CHINA 100039

- **Contact Person:**
  Ms. Yajing Li
  North Building 3F, No. 9 Shuangyuan Road,
  Badachu Hi-tech Zone, Shijingshan District Beijing China 100041
  Phone: +86-10-88790480 x 6046
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  Email: liyajing@choicemmed.com

- **Date prepared:**
  January 8, 2009

2. Applicant Device Information

- **Trade/Proprietary Name:** Pulse Oximeter MD300K1
- **Common Name:** Pulse Oximeter
- **Classification:** 21CFR 870.2700 Oximeter Class: II

3. Legally Marketed Predicate Device

Pulse Oximeter PM-60
K-number: K072581
Shenzhen Mindray Bio-medical Electronics Co., LTD

4. Description

The Pulse Oximeter MD300K1 can display %SpO2, pulse rate value and vertical bar graph pulse amplitude. It suits for adult and pediatric patients. The device has physiological alarm which includes PR high/low alarm and SpO2 high/low alarm. At the same time, the device has a buzzer which is used for sensor off indication, pulse indication, low voltage indication and PR & SpO2 alarm.

The pulse oximeter adapts 8-segment digital LED as indication. The applicant device has low battery voltage alarm function and automatically power of function. The device supplies a sensor as the accessory and uses 2 * AA batteries.

The MD300K1 Pulse Oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 940 nm, which is ultra red light.
Skin, bone, tissue, and venous vessels normally absorb a constant amount of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

5. Intended use

The MD300K1 Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult and pediatric patients in hospitals and home care.

6. Statement

This is a traditional 510(k) report for Pulse Oximeter MD300K1, which has the same intended use to PM-60 Pulse Oximeter (K072581).
The Pulse Oximeter MD300K1 is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult and pediatric patients in hospitals and home care, which is same as the predicate device Pulse Oximeter PM-60.

7. Substantially Equivalence Determination

Comparison Analysis
The applicant device has same classification information, same intended use, same design principle, same specifications, same product materials and performance effectiveness as the

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2009

Ms. Yajing Li
North Building 3F, No. 9 Shuangyuan Road,
Badachu Hi-tech Zone, Shijingshan District
Beijing CHINA 100041

Re: K090599
Trade/Device Name: MD300K1 Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 25, 2009
Received: July 6, 2009

Dear Ms. Yajing Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use

510(k) Number (if known): Pending

Device Name: MD300K1 Pulse Oximeter

Indications for Use:

The MD300K1 Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult and pediatric patients in hospitals and home care.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

)ivision Sign-Off)
)ivision of Anesthesiology, General Hospital
ection Control, Dental Devices

)(k) Number: K090599